CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

40257

ADMINISTRATIVE DOCUMENTS

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: **40-257** Date of Submission: **June 30, 1997**

Applicant's Name: **Mallinckrodt**

Established Name: **Oxycodone and Acetaminophen Capsules USP, 5 mg/500 mg**

Labeling Deficiencies:

1. CONTAINER 100s and 500s

   a. It is not necessary to include the statement "In addition, each capsule contains FD&C Yellow No. 6." on the label. Prescription drugs are required to list the presence of this ingredient in the insert labeling. We refer you to 21 CFR 201.20(c) for guidance.

   b. Improve the readability of the "+" sign.

2. INSERT

   a. DESCRIPTION

      i. Move the "Each capsule contains ..." statement and the paragraph listing the inactive ingredients to be the first and second paragraphs in this section.

      ii. Replace the sentence beginning "Acetaminophen occurs ..." with the following text:

      Acetaminophen, 4'-hydroxyacetanilide, is a non-opiate, non-salicylate analgesic and antipyretic which occurs as a white, odorless, crystalline powder with a slightly bitter taste. It has the ...

   b. INDICATIONS AND USAGE

      You may delete

c. CONTRAINDICATIONS

... patients who are hypersensitive to ...

d. PRECAUTIONS

i. Delete the numbers in front of the subsection titles.

ii. General

A). Acute Abdominal Conditions - ... course of patients ("of" rather than "in").

B). Special Risk Patients - Delete the word

iii. Drug Interactions

A). Delete the word

B). Delete the last paragraph (The use of ...)

iv. Usage in Pregnancy

A). Revise the subsection heading to read: **Pregnancy:**

B). Revise the sub-subsection heading to read: *Teratogenic Effects:* Pregnancy Category C:

C). Delete the word (3 instances).

D). Last sentence - Oxycodone and acetaminophen should not be ... to a pregnant woman unless in the judgment of the physician, the potential benefits outweigh the possible hazards.

v. Labor and Delivery

A). Delete the word in the first sentence.

B). Delete the last sentence (The effects of the drug ...)

vi. Nursing Mothers

Delete the word

e. OVERDOSAGE

i. Acetaminophen - Treatment, second sentence - Patients' estimates ...

ii. Oxycodone - Signs and Symptoms, first sentence - "overdosage" rather than "overdose".

f. DOSAGE AND ADMINISTRATION

i. Combine the two paragraphs.

ii. Last sentence - "dosage" rather than "dose".

g. HOW SUPPLIED

i. We note that this section describes your drug product as a "Red/Buff hard gelatin capsule imprinted with an M 532 identification number" while on page 464 the capsule is described as having a red cap with a beige body and the logo MGI 532 present. Please revise and/or comment.

ii. Please include the statement "DEA Order Form Required."

Please revise your labels and labeling, as instructed above, and submit in final print.

Please note that we reserve the right to request further changes in your labels and/or labeling based upon changes in the approved labeling of the listed drug or upon further review of the application prior to approval.

To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with your last submission with all differences annotated and explained.

/S/

Jerry Phillips
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research